Remarks

This application contains claims 1-364, the status of which is as follows:

(a) Claims 21, 32, 164, 175, 363, and 364 have been currently amended.

(b) Claims 22-25, 30-31, 33-45, 166, 168, 173-174, 176-181, 183-188, and 361-362 were previously presented.

(c) Claims 165, 167, and 182 are as originally filed.

(d) Claims 1-20, 26-29, 46-163, 169-172, and 189-360 were previously canceled.

No new matter has been added.

Claim rejections under 35 U.S.C. 102

Independent claims 21 and 164 were rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,473,644 to Terry, Jr. et al. While not necessarily agreeing with these rejections, in order to expedite issuance of a patent, Applicants have amended claims 21 and 164 to replace increasing atrial motion with modulating the applied current to cause fluctuation in atrial contractility sufficiently to reduce a risk of an occurrence of a thromboembolic event. This amendment emphasizes the originally-intended interpretation of the claim language, as disclosed in the specification as filed (see, *inter alia*, p. 53, line 13 - p. 54, line 3), and precludes the Examiner's broader interpretation of the previously recited increase in atrial motion. Conforming amendments have been made to dependent claims 32, 175, 363, and 364.

The Examiner argued that col. 8, line 57 - col. 9, line 18 of Terry discloses "configur[ing] the current to modify atrial motion of the subject sufficiently to reduce a risk of an occurrence of a thromboembolic event" (¶4 of the office action). This passage from Terry describes techniques for configuring vagal stimulation in order to reduce the ventricular rate toward a target rate, while maintaining atrial-ventricular synchrony. The passage makes no mention of a control unit configured to cause fluctuation in atrial contractility, as now recited in claims 21, or modulating the applied current to cause

fluctuation in atrial contractility, as now recited in claim 164. Indeed, the passage does not describe directly affecting the atrium in any way. The rest of Terry also fails to teach or suggest applying vagal stimulation to cause fluctuation in atrial contractility to reduce the risk of thromboembolic events.

Applicants thus respectfully submit that claims 21 and 164 are not anticipated by Terry. All of the other pending claims directly or indirectly depend from claim 21 or claim 164, and thus are also in condition for allowance.

Claim rejections under 35 U.S.C. 102 and/or 103

Claims 22, 24, 165, and 167 were rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Terry. Claims 23, 166, 361, and 362 were rejected under 35 U.S.C. 103(a) as being unpatentable over Terry. Claims 25 and 168 were rejected under 35 U.S.C. 103(a) as being unpatentable over Terry as applied to claims 21 and 164, and further in view of US Patent 5,928,269 to Alt. Claims 30, 31, 173, and 174 were rejected under 35 U.S.C. 103(a) as being unpatentable over Terry as applied to claims 21 and 164, and further in view of US Patent Application Publication 2003/0045909 to Gross et al. Claims 32, 35, 36, 37, 39, 42, 43, 175, 178, 179, 180, 182, 185, 186, 363, and 364 were rejected under 35 U.S.C. 103(a) as being unpatentable over Terry at applied to claim 21, and further in view of US Patent 6,341,236 to Osorio et al. Claims 44, 45, 187, and 188 were rejected under 35 U.S.C. 103(a) as being unpatentable over Terry as applied to claim 21, and further in view of Osorio. Claims 33, 34, 38, 176, 177, and 189 were rejected under 35 U.S.C. 103(a) as being unpatentable over Terry in view of Osorio as applied to claims 21 and 32, and further in view of Gross et al. Claims 40, 41, 183, and 184 were rejected under 35 U.S.C. 103(a) as being unpatentable over Terry in view of Osorio as applied to claims 21 and 32, and further in view of US Patent 6,256,537 to Stoop et al.

As mentioned above, all of these dependent claims are in condition for allowance because they depend from allowable independent claims. In addition, Applicants respectfully submit that at least the following dependent claims would be allowable even if the rejection of the independent claims were to be sustained.

Claims 22, 24, 165, and 167

As mentioned above, dependent claims 22, 24, 165, and 167 were rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Terry. The Examiner argued that "Because Terry teaches that coronary blood flow is increased through the heart, it is understood that blood flow within the atrium and out of the left atrial auricle would increase." Applicants respectfully disagree with this assertion. It is well known in the art that the coronary arteries originate from the ascending aorta, and that coronary blood flow occurs mainly during diastole, when the aortic valve is closed. Thus, any increase in coronary blood flow would cause (a) a corresponding decrease in blood flow through the aorta to the systemic circulation, rather than (b) an increase in blood flow out of the left ventricle and thus indirectly out of the left atrium. Therefore, the increase in coronary blood flow taught by Terry would not necessarily result in an increase in blood flow within the atrium and out of the left atrial auricle. A declaration under 37 C.F.R. 132 is submitted herewith providing evidence in support of this argument.

The Examiner also argued that "it would have been obvious . . . to modify the current that increases coronary blood flow as taught by Terry with a current that increases blood flow within the atrium and out of the left atrial auricle, since such a modification would provide the predictable results of improving cardiac output in order to treat a patient's cardiac insufficiency, such as atrial fibrillation." Applicants respectfully submit that the Examiner has failed to provide any reasons, arguments, or evidence why one of ordinary skill in the art, having learned Terry's vagal stimulation techniques to "enhance cardiac capillary growth and cardiac output in heart failure patients" (col. 1, lines 7-10), would have any expectation that such techniques would increase blood flow within the atrium. The Examiner has also offered no arguments why improved cardiac output would be a predictable result of such a theoretical modification to Terry's teachings. Furthermore, the techniques recited in independent claims 21 and 164 are directed toward reducing the risk of thromboembolic events, rather than improving cardiac output.

Applicants thus respectfully submit that dependent claims 22, 24,

165, and 167 are independently patentable over Terry.

Claims 23, 166, 361, and 362

As mentioned above, dependent claims 23, 166, 361, and 362 were rejected under 35 U.S.C. 103(a) as obvious over Terry. The Examiner argued that although Terry does not disclose that his techniques can be used for treating a subject suffering from atrial fibrillation or an increased risk of thromboembolic events, Terry does mention in his Background section that vagal stimulation is known for treating atrial fibrillation. The Examiner argued it would thus be obvious to use Terry's techniques for treating a subject suffering from atrial fibrillation, instead of a subject suffering from heart failure, as taught by Terry.

Applicants respectfully disagree with this assertion. In the first paragraph of his Summary section, Terry explicitly contrasts his techniques with known techniques for treating atrial fibrillation, and thus explicitly teaches against the substitution suggested by the Examiner:

> The present invention is directed to reducing the heart rate in patients suffering from heart failure--a reduction which may be and preferably is to a rate that is lower than the low end of the normal range of the heart rate of a human subject--to promote and enhance coronary capillary growth and coronary blood flow. This is to be contrasted, for example, with the method and purposes disclosed in the aforementioned '681 patent, which is primarily concerned with reducing a pathologic rapid heart rate--a rapid ventricular rate in the presence of atrial fibrillation--to a rate within the normal range, by using vagal stimulation. (col. 3, lines 31-40)

Applicants thus respectfully submit that dependent claims 23, 166, 361, and 362 are independently patentable over Terry.

The Examiner took official notice that "a thromboembolic occurrence is a common side effect of atrial fibrillation. Therefore, any treatment of atrial fibrillation would also treat thromboembolic occurrences because of the improved blood flow." Applicants

respectfully traverse this unsubstantiated assertion by the Examiner, and submit that not all treatments of atrial fibrillation would treat thromboembolic occurrences. Some treatments for atrial fibrillation, including those described in the Geddes patents mentioned by Terry in his Background section, attempt to minimize the undesirable effects of atrial fibrillation, rather than resolve the atrial fibrillation itself, and thus would not necessarily treat thromboembolic occurrences. For example, Geddes's techniques, as characterized by Terry, "control ventricular rate during atrial fibrillation" (col. 2, lines 40-47, emphasis added). Applicants thus respectfully traverse the Examiner's unsubstantiated assertion, and note that the "the examiner must provide documentary evidence in the next Office action if the rejection is to be maintained" (MPEP 2144.03).

Claims 25 and 168

As mentioned above, dependent claims 25 and 168 were rejected under 35 U.S.C. 103(a) as obvious over Terry and further in view of Alt. Applicants respectfully submit that one of ordinary skill in the art would not combine the AF sensor of Alt with the techniques of Terry, because Terry neither teaches nor suggests that the use of his techniques for treating AF, as discussed above. Applicants thus respectfully submit that dependent claims 25 and 168 are independently patentable over Terry in view of Alt.

Claims 32, 35, 36, 37, 175, 178, 179, 180, 363, and 364

As mentioned above, dependent claims 32, 37, 175, 180, 363, and 364 were rejected under 35 U.S.C. 103(a) as obvious over Terry and further in view of Osorio et al. Applicants respectfully disagree with these rejections for the following reasons:

- One of ordinary skill in the art would have no reason to combine Osorio with Terry. Terry teaches vagal stimulation for treatment of heart conditions, while Osorio teaches vagal stimulation for treatment of epileptic seizures (abstract). Furthermore, Osorio explicitly teaches against use of his techniques for affecting the heart in any way: "As discussed herein, it is preferred that the stimulation

be accomplished so as to have minimal effect on the heart" (col. 5, lines 21-23).

- Osorio fails to teach or suggest the cycling between the first and second stimulation periods recited in claims 32 and 175. The passage from Osorio cited by the Examiner reads in context: "At step 625, if it is determined that the vagus nerve stimulation needs to be adjusted, any number of approaches may be taken. . . . Another option is to automatically turn off the stimulation provided to the vagus nerve 60. A third option is to adjust the stimulation by adjusting the pulse frequency, amplitude, and/or width (discussed further herein)" (col. 10, lines 10-20). Osorio teaches a one-time adjustment or cessation of vagal stimulation, and provides absolutely no suggestion of cycling between first and second stimulation periods. (It is noted that although the word "cycling" appears at col. 5, line 18 of Osorio, it is clear from context that this is referring to the periodic shape of the applied signal, and not to alternatingly switching between two sets of parameters, as "cycling" clearly means when understood in context in the claims of the present application.)

- Osorio fails to teach configuring the current to cause a reduction in a force of contraction of atrial cells during the first periods, and an increase in the reduced force of contraction of the atrial cells during the second period. Even if Osorio were to teach cycling (which he does not), such cycling would not inherently reduce and increase atrial contractility.

Applicants thus respectfully submit that dependent claims 32, 37, 175, 180, 363, and 364 are independently patentable over Terry in view of Osorio. Claims 35 and 36 depend from claim 32, and claims 178 and 179 depend from 175, and thus are also allowable, because Terry fails to suggest cycling between two sets of parameters.

Claims 42, 43, 185, and 186

As mentioned above, dependent claims 42, 43, 185, and 186 were rejected under 35 U.S.C. 103(a) as obvious over Terry and further in

view of Osorio et al. Applicants respectfully submit that there would be no reason or motivation to combine Osorio with Terry, as discussed above. Furthermore, Osorio entirely fails to mention initiating stimulation periods within about 50 milliseconds of the occurrence of a QRS-complex, or otherwise synchronized with the QRS-complex. Osorio merely teaches detection of a QRS-complex as one way for sensing heart rate (col. 4, lines 54-57). Applicants thus respectfully submit that dependent claims 42, 43, 185, and 186 are independently patentable over Terry in view of Osorio.

Claims 38 and 181

As mentioned above, dependent claims 38 and 181 were rejected under 35 U.S.C. 103(a) as obvious over Terry and further in view of Osorio et al., and further in view of Gross et al. Applicants respectfully submit that there would be no reason or motivation to combine Osorio with Terry, and that Osorio does not teach cycling between stimulation periods, as discussed above. Furthermore, the Examiner made no arguments regarding why modifying the alleged teaching of Osorio to induce and block currents during first and second periods, respectively, would produce "predictable results." Applicants thus respectfully submit that dependent claims 38 and 181 are independently patentable over Terry in view of Osorio and further in view of Gross.

Claims 40, 41, 183, and 184

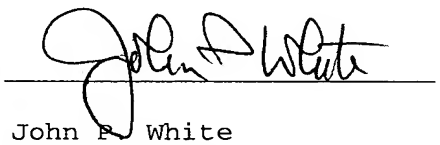
As mentioned above, dependent claims 40, 41, 183, and 184 were rejected under 35 U.S.C. 103(a) as obvious over Terry and further in view of Osorio et al., and further in view of Stoop et al. Applicants respectfully submit that there would be no reason or motivation to combine Osorio with Terry, and that Osorio does not teach cycling between stimulation periods, as discussed above. Furthermore, Applicants respectfully submit that there would be no reason or motivation to combine the cardiac pacing techniques of Stoop with the vagal stimulation techniques of Terry or Osorio. Applicants thus respectfully submit that dependent claims 40, 41, 183, and 184 are independently patentable over Terry in view of Osorio and further in view of Stoop.

Applicants believe the amendments and remarks presented hereinabove to be fully responsive to all of the grounds of rejection raised by the Examiner. In view of these amendments and remarks, Applicants respectfully submit that all of the claims in the present application are now in order for allowance. Notice to this effect is respectfully requested.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee, other than the $65.00 fee for a one (1) month extension of time, is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



John P. White
Registration No. 28,678
Attorney for Applicants
Cooper & Dunham LLP
30 Rockefeller Plaza
New York, New York 10112
(212) 278-0400

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

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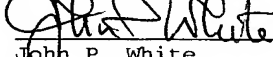

6/4/09

John P. White Date
Reg. No. 28,678

Appendix

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Application of	: Omry BEN-EZRA et al.
Appl. No. : 10/560,654	: Group Art Unit: 3762
Filed : May 1, 2006	: Examiner: J. Dietrich
Confirmation No. : 2254	:

For : VAGAL STIMULATION FOR ANTI-EMBOLIC THERAPY

RULE 132 DECLARATION OF TAMIR BEN-DAVID

I, the undersigned, Tamir Ben-David, of 55 Mivtsa Kadesh Street, Tel Aviv, Israel, hereby declare as follows:

1. I am one of the Applicants in U.S. Patent Application No. 10/560,654 (hereinafter "the application").

2. I have been employed as a professional in the field of medicine and medical devices for eight years. I am currently employed as VP of Business Development at BioControl Medical Ltd. (hereinafter "BioControl"), the assignee of the application. I was previously employed as VP of Neurocardiology of BioControl for three years, and as CEO of Biological Signal Processing (BSP) Ltd. for 2.5 years. I received a Ph.D. from Tel Aviv University.

3. Over the past nine years, I have invented and developed a variety of medical devices. I have participated actively, as an inventor, designer and as a manager, in the development of several medical devices, including the HyperQ stress test system and the Cardiofit System, a vagus nerve stimulator for treating heart conditions. I have conducted numerous animal experiments in which nerve stimulators similar to those described in the application were implanted and configured to apply various nerve stimulation protocols.

4. Claims 22, 24, 165, and 167 were rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Terry. The Examiner argued that "Because Terry teaches that coronary blood flow is increased through the heart, it is understood that blood flow within the atrium and out of the left atrial auricle would increase."

5. It is well known in the art that the coronary arteries originate from the ascending

aorta, and that coronary blood flow occurs mainly during diastole, when the aortic valve is closed. Thus, any increase in coronary blood flow would cause (a) a corresponding decrease in blood flow through the aorta to the systemic circulation, rather than (b) an increase in blood flow out of the left ventricle and thus indirectly out of the left atrium.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and conjecture are thought to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application of any patent issued thereon.

Tamir

Tamir Ben-David, Citizen of Israel
55 Mivtsa Kadesh Street, Tel Aviv
May 11, 2009